EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. SYSTEM PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO: ***Deborah Phillips v. Ethicon, Inc., et al.***	**HON. JOSEPH R. GOODWIN**

RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and

pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly 3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT-O-O mid-urethral sling. I am familiar with the Ethicon TVT-O-O system, its construction, intended use, method of implantation and potential risks through my clinical treatment of patients, my review of discovery materials in this litigation as well as the similarities of the TVT-O-O to the transvaginal mesh products of other companies. I have personally treated patients who have suffered complications from the Ethicon TVT-O-O mesh product and I am familiar with how this particular product may cause injuries to patients, including to Ms. Phillips.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT-O-O played in causing injury to Ms. Phillips. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, the reports of other experts as specified in my reliance list, and a review of relevant medical records pertaining to Ms. Phillips. All of my opinions are true and correct to the best of my knowledge. Further, all of the opinions that I offer in this report I hold to a reasonable degree of medical and scientific certainty. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, depositions, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Phillips.

B. Summary of Materials Reviewed.

In addition to those items referenced in my reliance list, I have reviewed the following medical records, documents and depositions with accompanying exhibits pertaining to Deborah Phillips:

Ahmed Nasim, MD

Inas Al-Attar, MD

Associated Pathologists

Beckley ARH Hospital

Bland County Med Clinic

Blue Ridge Internal Medicine

Bluefield Gastroenterology

Charleston Area Medical Center

Broward Outpatient

Matthew Denti, DO

Dermatology Associates and Surgery Center

Rowena Gonzales Chambers, MD

Greenbrier Valley Medical Center

Greenbrier Valley Urology Associates

Hickman Pharmacy

Jamette Huffman, DO

Brandon Lingenfelter, DO

Marshall Family & Internal Medicine

Mena Ashraf, MD

Mercer Medical Group

William Merva, MD

Midtowne Family Practice

Mon Health Digestive Care

New River Health

Princeton Community Hospital

Robert Kropac, MD

Ujjal Sandhu, MD

Vishnu Patel, MD

At the time of trial, I intend to use the medical records referenced herein as well as the articles, literature and other documents identified in Appendix 1 to my report. I may also utilize medical diagrams, models and demonstrative aides during my trial testimony. I reserve the right to utilize summaries of medical records and documents referenced herein. I further reserve the right to reference and utilize any exhibit identified by Defendants' experts in my field of expertise at the time of trial. I reserve the right to utilize any additional records that are discovered in this case.

Summary of Medical Facts related to Deborah Phillips

DOB

9/9/1963

Past Medical History:

Diabetes, Neurogenic Bladder, GERD, Gastroparesis, Right Breast Cancer (DCIS), VAIN, Vulvodynia, Hydrosalpinx, COPD, LTCS, Foot Surgery, Depression, Anxiety, Insomnia, HTN

Past Surgical History:

Vaginal Hysterectomy (1998), Herniorrhaphy, Sling Removal (2014), Skin Biopsies, Oophorectomy (2017), Vulvectomy, Cervical Dysplasia/cancer (1984), Operative Laparoscopy, Fundoplication(dysphagia)

Medications

Carvedilol (beta blocker), Lasix, Temazepam, Promethazine, Elavil, Pantoprazole, Dexilant, Chantex, Combivent, Prozac

9/5/2017

She was seen at her PCP. Her neurogenic bladder was addressed with Vitamin D and Carvedilol.

5/11/2017

She had a BSO. There were no pelvic or abdominal adhesions

4/25/2017

She was referred to Dr Lingenfelter for pelvic pain. The ultrasound was normal. She had a colonoscopy that was negative. She reports continued pain for the past 3 months. She feels that

the pain is constant without modifying factors. She wants her ovaries removed due to chronic pain.

3/16/2017

Annual examination for interstitial cystitis.

3/13/2017

She saw Dr Tucker and was evaluated for pelvic pain. Her vaginitis panel was negative.

3/2/2017

Dr tuckers office for vaginal itching after antibiotics. She is without urinary symptoms. She had tenderness of left adnexa.

2/20/2017

She presented as a new patient. She reports urinary symptoms. She was found to have vaginal atrophy. The lower 2/3 of the vulva (perineum and introitus) has been excised. Urethra was normal.

2/24/2016

Negative urine collection. She was incomplete bladder emptying and urge incontinence.

9/21/2015

She was found to have an E. coli UTI.

12/3/2014

Dr Pescatore

She was a 51-year-old who presents to the office for evaluation. She had a Gynecare TVT-O-O in July 2007. The patient had stated that she did not have relief after her surgery. She reported that after her surgery she started to have UTIs. She continued with prophylactic antibiotics for 3 years. She reports continued difficulty with voiding. She has pain with voiding and has feeling of incomplete emptying. She reported pelvic pain and dyspareunia. She also complains of

frequency, nocturia and urge incontinence. On physical examination: her anterior wall demonstrates tenderness over the mid urethra. The sling is palpable. The plan was for surgical revision, Urethrolysis and partial vaginectomy.

12/4/2014

She underwent a sling revision, Urethrolysis, partial vaginectomy. During the surgery, the sling was noted to be quite tight and disrupted the long axis of the urethra. The sling has significant scarification and evidence of periurethral erosion.

12/12/2013

She reports urinary urgency and incomplete bladder emptying. She had a PVR 58 ml.

11/21/2012

She was seen for urinary urgency. She had a normal bladder scan

5/5/2011

She was seen for recurrent UTIs. She was being treated with Macrobid daily and Vesicare.

4/3/2011

She had a blue spot on vaginal wall. She reports vaginal discharge and itching.

10/28/2010

She has side effects with Ditropan and would like to switch to Vesicare.

9/7/2010

She was treated for an UTI.

7/26/2010

GI physicians she was seen for fluid around her intestines.

4/22/2010

She was seen by Dr. Kropac for chronic low back pain.

2/24/2010

She has urge incontinence and an UTI (December 2009). She was treated with Vesicare.

12/21/2009

She was diagnosed squamous cell carcinoma in situ. She had a 4 x 2 cm vulvar lesion (left) and a 2.5 x 1 cm on right. She had a partial vulvectomy.

12/2/2009

She was treated for an UTI with Cipro.

6/17/2009

She had a colposcopy for vaginal dysplasia.

12/2/2008

She presented for annual examination. She reports a sore on her labia that won't heal since 9/2007 when Dr Fort did bladder surgery. Examination: lesion under left inferior labia minora. She was referred for vulvar lesion.

10/8/2008

She has minimal dysuria and has been off all medications for the past month. She has previously failed Enablex. She reports her urgency has resolved.

5/14/2008

She failed Enablex and was placed on Vesicare.

11/28/2007

She reports trouble with urinating, "has the urge". No leakage. She stopped Enablex

7/24/2007

She had surgery for SUI with a TVT-O-O.

6/20/2007

She presented for a 6 month follow up visit. She had a hypermobile urethra with an unstable bladder. She did not get improvement with Enablex. It was recommended that she have as TVT-O-O.

12/20/2006

She had a cystoscopy. She was started on Enablex.

11/30/2007

Normal examination

11/29/2006

She would like SUI fixed. She also has dyspareunia. She has an enterocele on examination. She was referred to Dr Forte.

9/30/2005

She reports right lower quadrant pain. Dr Huffman felt it was likely recurrence of pelvic adhesions.

9/22/2004

She is feeling a lot of pelvic pressure that is different than previous. She has rectal bleeding. She had a normal pelvic examination.

10/23/2003

She has continued left lower quadrant pain, occasionally. Otherwise pain is 100% gone.

Methodology and Analysis.

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. In addition, this chronic inflammation/infection could be a source of any future erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Similar opinions and information have been stated and discussed in the expert reports of Dr. Uwe Klinge and Dr. Paul J. Michaels, and I rely, at least in part, on these reports in reaching the conclusions made herein. Ethicon's Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the pelvic pain and dyspareunia suffered by Deborah Phillips, I consider her pelvic floor surgery and the use of mesh. I concluded that her TVT-O sling caused pain. Her surgeon noted tenderness along her mid-urethra with significant scarring along the urethra with some periurethral erosion. Further chronic pain caused by what Dr. Rosenzweig refers to as a chronic inflammation from the mesh.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from her hysterectomy and pelvic surgery. she has many factors that can contribute to her pain. These include: neurogenic bladder, vulvectomy, vulvodynia, hydrosalpinx, C-section, oophorectomy, frequency and urgency syndrome and interstitial cystitis. After her partial sling removal, Ms. Phillips had continued pelvic

pain. I considered each of these other risks for her pain and I concluded that they could not be ruled out as a contributory source of pain suffered by Deborah Phillips.

It is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Deborah Phillips's treating physician met the standard of care during implantation of the TVT-O device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications. Finally, I believe that Ms. Phillips was an appropriate candidate for the procedures at the time or her implants.

C. Conclusion.

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that Ms. Phillips's TVT-O Mesh Implant was painful to touch on examination. This pain is caused by chronic inflammation around the mesh caused by the TVT-O Mesh Implant's polypropylene construction.

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All of the opinions expressed in my report are held to a reasonable degree of medical certainty. I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 10nd day of December

William Porter, M.D.